IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION (TOLEDO)

TINA BURRIS, Plaintiff, v. ETHICON, INC., et al., Defendants.	CASE NO. 3:20-cv-01450 JUDGE JAMES R. KNEPP II **DEFENDANTS' TRIAL BRIEF**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon" or "Defendants"), by and through counsel, hereby submit the following Trial Brief pursuant to the Court's April 5, 2022 Trial Order (Doc. 182).

I. STATEMENT OF THE FACTS

Plaintiff Tina Burris ("Ms. Burris") is a 56-year-old married mother of three adult children who underwent a Prolift anterior surgery in August 2008. Prolift is a medical device intended to treat pelvic organ prolapse. Ms. Burris has alleged that the Prolift device has caused her to experience pudendal neuralgia and/or muscle damage causing groin, leg, and vaginal pain; chronic pelvic pain; pain with intercourse; and painful bladder-filling syndrome.

Prior to her 2008 surgery, Ms. Burris had a history of severe pelvic pain. On February 19, 2008, OB/GYN Dr. Desrene Brown performed a hysterectomy to address this pain. On July 28, 2008, Dr. Brown consented Ms. Burris for treatment of a symptomatic cystocele, or prolapse of her bladder, with pelvic mesh. At the time of this consultation, Dr. Brown was aware of the risk that patients implanted with Prolift would develop an erosion or exposure, chronic pain with sexual intercourse, chronic pelvic pain, urinary problems including pain with urination, organ damage, nerve damage, neuromuscular problems in the pelvic floor muscles or lower

extremities, recurrent prolapse, or would require additional surgery to treat an adverse outcome. Dr. Brown implanted Ms. Burris with an anterior Prolift on August 5, 2008.

After surgery, Ms. Burris developed an exposure of mesh into the vagina that was removed with scissors in the office on September 17, 2008. She also developed complaints of persistent pelvic pain and pain with intercourse. On November 15, 2011, she underwent a vaginal excision of her Prolift by Dr. Mark Walters to address eroded mesh, pelvic pain, and vaginal pain. The surgery was complicated by a puncture of the bladder and transection of her left ureter, both of which were repaired intraoperatively.

Ms. Burris continued to have post-operative complaints of pain. In 2015, she was treated for interstitial cystitis and painful bladder, chronic pelvic pain, and pudendal neuralgia. Despite treatment, her pain persisted, and in late 2015 she developed a recurrent prolapse. On August 2, 2015 her prolapse was treated with a vaginal vault suspension and anterior and posterior repairs by Dr. Mark Walters.

Ms. Burris continued to have pain after her 2015 surgery, including worsening right thigh pain. On October 20, 2021 she underwent removal of Prolift mesh from the right vaginal wall and thigh by Dr. Howard Goldman.

II. CONTROLLING LAW

Plaintiff Tina Burris alleges that Defendants failed to provide an adequate warning about the potential risks of Prolift to ordinary users of the product, including herself, in violation of Ohio's Product Liability Act ("OPLA"), R.C. 2307.76 ("Product defective due to inadequate warning or instruction"). Failure to warn under the OPLA is Plaintiff's *only* remaining cause of action following this Court's July 28, 2021 Order, in which this Court granted Defendants' Supplemental Motion for Partial Summary Judgment and dismissed Plaintiff's design-defect

claim. *See* Memorandum and Order (Doc. 105) at 17. This section of the brief sets out Ohio law as it relates to Plaintiff's failure-to-warn and punitive damages claims.

A. Failure to Warn

1. Plaintiff's Burden of Proof

The OPLA provides that a product is defective due to inadequate warning or instruction if, at the time it left the control of its manufacturer, *both* of the following applied:

> (1) The manufacturer knew or, in the exercise of reasonable care, should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages; and
>
> (2) The manufacturer failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk, in light of the likelihood that the product would cause harm of the type for which the claimant seeks to recover compensatory damages and in light of the likely seriousness of that harm."

R.C. 2307.76(A)(1). Thus, a plaintiff seeking to establish a failure-to-warn claim under the OPLA bears the burden of proving each of the following elements by a preponderance of the evidence: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury that is proximately caused by this breach. *Fulgenzi v. PLIVA, Inc.*, 140 F. Supp.3d 637, 647 (N.D. Ohio 2015) (quoting *Monroe v. Novartis Pharm. Corp.*, 29 F. Supp. 3d 1115, 1125 (S.D. Ohio 2014)).

2. Learned Intermediary Doctrine

In failure-to-warn cases involving medical devices, a defendant's duty to warn is limited when the product is prescribed and implanted by a "learned intermediary." *Fulgenzi*, 140 F. Supp. 3d at 648-49. Recognized under Ohio law and codified at R.C. 2307.76(C), the learned intermediary doctrine provides that a drug manufacturer satisfies its duty to warn of known risks by providing an adequate warning *to the medical professional* of the risks associated with the drug's use. *Id.*; *see also Vaccariello v. Smith & Nephew Richards, Inc.*, 94 Ohio St.3d 380, 763

N.E.2d 160, 164 (2002). As R.C. 2307.76(C) explains, the learned intermediary doctrine exempts a manufacturer from liability for an inadequate warning or instruction when the:

> manufacturer provides [an] otherwise adequate warning and instruction to the physician or otherwise legally authorized person who prescribes or dispenses [an] ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it.

This reflects a recognition "that the physician stands between the manufacturer and the patient as a learned intermediary" with a "duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." *Vaccariello*, 94 Ohio St.3d at 384. "The physician is in the best position, therefore, to balance the needs of patients against the risks and benefits of a particular drug or therapy, and then supervise its use." *Id*. The Ohio Supreme Court extended the doctrine to prescription medical devices in *Vaccariello*. *Id.*

In addition, under Ohio law, Defendants do not have a duty to warn about risks that are open and obvious or a matter of common knowledge. *See* Ohio Rev. Code § 2307.76(B) (A product is not defective for inadequate warnings as to "a risk that is a matter of common knowledge."). "Whether a risk meets the 'common knowledge' standard 'is determined by reference to the industry in which the product is used.'" *American Winds Flight Academy v. Garmin Intern.*, Nos. 5:07 CV 3401, 5:07 CV 3402, 2010 WL 3783136, *7 (N.D. Ohio Sep. 17, 2010) (quoting *Midwest Specialties, Inc. v. Crown Indus. Prods.*, 940 F. Supp. 1160, 1167 (N.D. Ohio 1996)). The relevant "industry" here is pelvic floor surgeons, as they are the category of medical professionals who implant Prolift.

3. Post-Marketing Failure to Warn Claim

With the submission of Plaintiff's Brief Regarding Deposition Objections (Doc. 193) on May 24, 2022, Defendants for the first time became aware that Plaintiff intends to argue that Prolift is defective due to inadequate *post-marketing* warnings or instructions. Plaintiff should be prohibitted from recovery under this theory, both because she failed to provide the required notice to Defendants pursuant to Fed. Civ. R. 8(a) and because there is insufficient evidence to permit her to recover under any such claim.

Plaintiff initially filed her action in Missouri Circuit Court as part of a multi-plaintiff complaint on March 26, 2013. After the action was removed to the Ethicon MDL and severed, Plaintiff filed her individual Short Form Complaint in the MDL. (Doc. 1.) By filing that Short Form Complaint, Plaintiff adopted the allegations in the First Amended Master Long Form Complaint and Jury Demand ("Master Complaint") entered in that action. *See* Pretrial Order # 15, *In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D.W.V.) (9/26/2012), attached here as Exhibit A. The Short Form Complaint allows a plaintiff to make allegations in addition to those included in the Master Complaint, but Plaintiff did not elect to do so, resting only on the Master Complaint's allegations.

The Master Complaint, attached here as Exhibit B, includes as Count III a claim of Strict Liability – Failure to Warn. The Count itself is silent as to the timing of the warnings alleged to be inadequate, *i.e.* at the time of marketing as opposed to post-marketing. The facts alleged in Section IV of the Master Complaint, however, relate *only* to warnings at the time of marketing, thus confirming that a post-marketing claim was not part of Plaintiff's allegations. Moreover, the Master Complaint allegations assert that the known complications of the pelvic mesh products in the mesh litigation were not as "described in [Defendants'] Patient Brochures, Instructions for Use, and other marketing materials" used *at or before* the time of an implant surgery. Master

Complaint at ¶ 27. The Master Complaint links the alleged deficiencies in the warnings and instructions to a motive of Defendants to increase sales. *Id.* at ¶ 46. ("the Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products"). Further, it contains allegations explicitly stating that the products were defective at the time of marketing. *Id.* at ¶ 80 ("The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health safety."). There are no corresponding facts or allegations related to post-marketing warnings.

The Master Complaint is pleaded neither under Ohio law nor the Ohio Product Liability Act ("OPLA"). Here, however, the parties have agreed that Ohio substantive law and the OPLA apply. *See* Pl. Resp. in Opp. to De. Partial MSJ (Doc. 38). The OPLA's failure to warn claim, codified at Ohio Rev. Code § 2307.76(A) does include separate sections relative to warnings at the time of marketing (§ 2307.76(A)(1)) and post-marketing warnings (§ 2307.76(A)(2)), but prior to last week Plaintiff had never indicated an intent to pursue a post-marketing warnings claim. In fact, when the parties jointly submitted their proposed jury instructions on March 14, 2022, it was uncontested that the failure to warn instruction given was *only* to include section (A)(1) – warnings at the time of marketing – with no mention of post-marketing warnings. Doc. 175 Instruction No. 40, pp. 45-47. Only now has Plaintiff belatedly sought to add a post-marketing warning instruction that was never mentioned when this Court first met with the parties to address jury instructions at the March 21, 2022 pretrial conference.

Federal Rule of Civil Procedure 8 requires a plaintiff to give notice of the nature of any claims asserted against a defendant and the relief that might be due. *See Atlas Chemical Industries, Inc. v. Moraine Products*, 509 F.2d 1, 7 (6th Cir. 1974). Further, "[t]he complaint must give the defendants fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Bassett v. National Collegiate Athletic Assoc.*, 528 F.3d 426, 437 (6th Cir. 2008) (internal quotations omitted). In the absence of fair notice, the Sixth Circuit has declined to allow plaintiffs to pursue claims that were not pleaded. *Id.* ("As Bassett was represented by counsel at the filing of the Complaint, we will not give such a liberal construction to allow a breach of contract claim when no such claim was pled.")

Here, Plaintiff has belatedly, less than two months before trial, decided to take advantage of a cause of action provided for by Ohio law but that she did not plead, on which the parties have not exchanged discovery, and on which the key witnesses have not been deposed. Plaintiff has been represented by counsel at all stages of this litigation and had the ability to incorporate specific causes of action under the OPLA at the time she filed her Short Form Complaint in the MDL. She did not do so. Instead, she adopted the allegations in the Master Complaint, which do not include allegations of injury due to post-marketing warnings or instructions. At this late juncture, Defendants would prejudiced by having to prepare a defense to this new allegation for which they were provided no notice. This prejudice is heightened by the fact that trial has already been delayed once and rectifying the prejudice caused by Plaintiff's eleventh-hour addition of a post-marketing claim would require additional new discovery that would in all likelihood delay the upcoming trial further.

Further, even if Plaintiff could properly raise a post-sale duty to warn claim at this late hour, it is inappropriate for inclusion in the upcoming trial due to the lack of any evidence in the

record directed at the issue of proximate cause, which remains an essential element of a post-sale duty-to-warn claim. *See Holland v. FCA US LLC*, 656 F. App'x 232, 239 (6th Cir. 2016) (concluding that a post-sale duty to warn claim should be dismissed due to the lack of any allegations sufficient to show that a post-sale duty to warn was the proximate cause of the plaintiff's injuries). There is no fact or expert evidence that any post-sale (meaning post-*implant*) warnings would have affected Plaintiff, her implanting physician, or her other treating physicians. In other words, Plaintiff has neither evidence of how any of her physicians would have reacted to post-implant warnings nor expert evidence about how a different post-implant course of treatment (if prompted by post-sale warnings) would have affected her eventual prognosis, both of which are relevant to the issue of proximate causation.

4. Proximate Cause

Even if a plaintiff can prove the breach of a duty to provide an adequate warning under the OPLA, the plaintiff must still prove that an inadequate warning was the "proximate cause" of her injuries—an inquiry that necessarily requires consideration of whether and how an adequate warning would have affected the physician's decision. Specifically, Plaintiff must prove that her implanting surgeon—here, Dr. Brown—*relied on* an inadequate warning from Defendants. *Fulgenzi*, 140 F. Supp. 3d at 649 ("A plaintiff 'not only must convince the fact finder that the warning provided is unreasonable, hence inadequate, but he also must establish the existence of proximate cause between the [product] and the fact of the plaintiff[']s injury.'") (quoting *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 936 (S.D. Ohio 2010)). In analyzing proximate cause issues, the Ohio Supreme Court has "divided proximate causation . . . into two sub-issues: (1) whether the lack of adequate warnings contributed to the plaintiff's [use of the product[], and (2) whether [use of the product] constitute[d] a proximate cause of the plaintiff's injury." *Id.* (quoting *Hisrich v. Volvo Cars of N. Am., Inc.*, 226 F.3d 445, 451 (6th Cir. 2000)).

Ohio courts evaluating proximate cause under the OPLA recognize that an inadequate warning "cannot be the proximate cause of a plaintiff's injuries if the user of the product failed to read the warnings accompanying the product." *Id.* at 649. This applies with equal force to drug and medical device cases; "an inadequate warning in a prescription package insert cannot be the proximate cause of a resulting injury if the physician did not read the insert prior to prescribing the medication." *Id.* Thus, to overcome the impact of the learned intermediary doctrine on her case, Plaintiff must prove both: (1) "that her implanting physician was aware of the alleged inadequate warning made by Defendants," *and* (2) "that her physician would have acted differently had he been given an adequate warning."[1] *Heide v. Ethicon, Inc.*, No. 4:20CV160, 2020 WL 1322835, at *5 (N.D. Ohio Mar. 20, 2020).

B. Punitive Damages

1. Well-established choice-of-law rules require this Court to apply Ohio punitive damages law.

Ohio punitive damages law applies to this case under the choice-of-law rules of Missouri, which direct this Court's choice-of-law analysis. As noted above, this action was initially filed in Missouri Circuit Court prior to its removal to the Ethicon MDL. When Plaintiff filed her individual Short Form Complaint in the MDL, she reaffirmed the State of Missouri as her forum of choice, indicating that the district court and division in which venue would be proper absent direct filing was "State of Missouri – Eastern Division." Doc.1 at p. 1. The case was remanded to the Northern District of Ohio on July 1, 2020.

The Sixth Circuit has held that "the court of proper venue should apply its own choice-of-law rules, not those of the MDL court." *Wahl v. General Elec. Co.*, 786 F.3d 491, 497 (6th Cir.

[1] In addition to the failure of notice, an additional reason not to permit an instruction regarding post-marketing failure to warn to go to the jury is that there is no evidence indicating that any of Plaintiff's physicians, had they received a different *post-marketing* warning, would have acted differently.

2015). The Sixth Circuit has further made a distinction between transfers for the convenience of the parties, pursuant to 28 U.S.C. § 1404(a), and transfer for improper forum, pursuant to 28 U.S.C. § 1406(a). Instances where a transfer is made for the former reason—which is the case here—require the court to apply the law of the transferor district, whereas the latter scenario results in application of the law of the transferee district. *Id.* The Sixth Circuit's reasoning was that plaintiffs should be allowed the benefit of their initial choice of an appropriate forum but not be allowed to benefit from having brought an action in an impermissible forum. *Id.* Applying this reasoning, the *Wahl* court affirmed a Tennessee district court's decision that Tennessee choice-of-law rules governed the claims of a Tennessee patient who directly filed her product liability claims against a New Jersey drug manufacturer in an Ohio multidistrict litigation pursuant to an MDL panel order. *Id.*at 493-94.

The posture of this case differs significantly from the underlying case considered in *Wahl* because, while the case was transferred from an MDL, it was initially filed in a different forum from which it was removed. As a result, there are three forums involved here, Missouri—the initial forum of filing; West Virginia—the MDL forum; and Ohio—the forum to which the case was ultimately transferred. Applying the principles of *Wahl* and assuming that Missouri was a proper forum for initial filing, Plaintiff should be given the benefit of the choice-of-law rules of Missouri, the forum of her choosing.

When determining choice-of law issues, Missouri courts apply the "most significant relationship" test established by the Restatement (Second) of Conflict of Laws. *Kennedy v. Dixon*, 439 S.W.2d 173, 184 (Mo. banc 1969). "[F]or personal injury actions, Missouri applies the law of the place of injury, unless some other state has a more significant relationship." *Winter v. Novartis Pharmaceuticals Corp.*, 739 F.3d 405, 410 (8th Cir. 2014), citing *Thompson v*

Crawford, 833 S.W.2d 868, 870 (Mo. banc 1992). The relevant contacts to be considered include: "(1) the place of the injury; (2) the place of misconduct; (3) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (4) the place where the relationship between the parties is centered." *In re NuvaRing Products Liability Litig.*, 957 F.Supp.2d 1110, 1114 (E.D. Mo. 2013).

Ohio is not only the place of injury, but also has the most significant relationship to this case. Ms. Burris, an Ohio resident, was implanted with Prolift in Ohio and developed her complications while living in Ohio. Her implanting physician was practicing in Ohio when she reviewed the instructions for Use for the Prolift. Ethicon, Inc. and Johnson & Johnson are New Jersey corporations with their principal places of business in New Jersey, but the relationship between the parties, which arises solely through this litigation, is centered in Ohio. *See In re NuvaRing*, 957 F.Supp.2d at 1115, citing *In re Air Crash Disaster Near Chicago, Illinois on May 25, 1979*, 644 F.2d 594, 612 n. 20 (7th Cir. 1981). And while New Jersey may have an interest in its corporations being governed by its punitive damages provisions, Ohio has a strong interest in applying its punitive damages laws to deter conduct by corporations doing business in Ohio that harms Ohio residents. *See Winter*, 739 F.3d at 410.

New Jersey's interest, balanced against Ohio's, does not overcome Missouri's presumption that the law of the place of injury should apply. *See id.* (holding in a pharmaceutical action that Missouri has a more significant relationship to a punitive damages claim than New Jersey under Missouri's choice-of law approach); *see also In re NuvaRing*, 957 F.Supp.2d at 1115 (same).

Moreover, while Missouri's choice-of-law provisions control, the result would be the same even if Plaintiff's case was *not* properly filed in Missouri at the time of the initiation of this

action. Then, under the *Wahl* principles, the choice-of-law rules of Ohio, the proper forum, would apply. The outcome would be the same, however, because Ohio also applies the Restatement (Second) of Conflict of Laws principles, which presumes "the law of the place of injury controls unless another jurisdiction has a more significant relationship to the lawsuit." *Morgan v. Biro Mfg. Co., Inc.*, 474 N.E.2d 286, 289 (Ohio 1984). Under this authority and analysis, Ohio intermediate courts analyzing choice of law for punitive damages in product liability cases have applied the law of the place of injury. *See, e.g.*, *Linert v. Foutz*, 20 N.E.3d 1047, 2014-Ohio-4431, ¶¶ 196-205 (Ohio Ct. App.) (applying Ohio punitive damages law to a product liability case arising from a car accident that took place in Ohio, with Ohio plaintiffs suing a Michigan manufacturer), *rev'd on other grounds*, 75 N.E.3d 1218, 2016-Ohio-8445; *see also In re E.I. du Pont de Nemours and Co. C-8 Personal Injury Litig.*, 316 F.Supp.3d 1021, 1032-34 (S.D. Ohio 2015) (holding in a product liability action that the law of the place of injury would apply under Ohio's choice-of-law approach).

2. Ohio's exemption from punitive damages in cases where a product had been approved of or licensed by the FDA applies.

Plaintiff cannot establish a claim for punitive damages because her substantive claim fails.[2] Further, Defendants are exempt from punitive damages under Ohio Rev. Code §

[2] Alternatively, punitive damages are inapplicable because Plaintiff cannot establish the standards for punitive damages set forth under Ohio law as a matter of law. A defendant cannot be held liable for punitive damages absent clear and convincing evidence that the alleged harm was the result of misconduct by Defendants that manifested a "flagrant disregard" for the safety of persons who might be harmed by the product in question or "actual malice." *See* Ohio Rev. Code § 2307.80(A); *Calmes v. Goodyear Tire & Rubber Co.*, 575 N.E.2d 416, 419 (Ohio 1991); *Preston v. Murty*, 512 N.E.2d 1174 (Ohio 1987), syllabus. It is not enough that a jury may find a product is defective to establish flagrant disregard or actual malice. Instead, there must be a "great probability of causing substantial harm." *Calmes* at 419; *see also Cabe v. Lunich*, 640 N.E.2d 159, 162 (Ohio 1994). No such evidence exists here. On the contrary, the evidence shows that, in developing Prolift, Ethicon acted in good faith to provide a product to help women suffering from the serious and often life-altering condition of pelvic organ prolapse. Plaintiff cannot establish, by clear and convincing evidence, a flagrant disregard for the safety of those

2307.80(C)(1) because Prolift was cleared for use by the FDA. Under that section, a manufacturer of a device, such as Ethicon—"shall not be liable for punitive or exemplary damages in connection with a product liability claim if the . . . device that allegedly caused the harm . . . was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the "Federal Food, Drug, and Cosmetic Act," as that law may be amended from time to time. Ohio Rev. Code § 2307.80(C)(1)(a). Ohio federal courts have applied this section to prohibit punitive damages in cases involving medical devices that have been cleared under the FDA's 510(k) process, like Prolift. *See, e.g.*, *Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, *2-3, 18-19 (S.D. Ohio Dec. 4, 2015) (applying Section 2307.80(C)(1)(a) to an FDA-cleared device); *see also Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2014 WL 2874268, *9 (S.D. Ohio June 24, 2014) (equating 510(k) clearance with approval for purposes of Section 2307.80(C)(1). As such, Defendants intend to move for directed verdict as to Plaintiff's punitive damages claim.

3. This Court should bifurcate evidence of the calculation of punitive damages issues from liability evidence during trial.

Defendants request, pursuant to Fed. R. Civ. P. 42(b), that the Court employ modified bifurcation by which evidence of liability for both compensatory and punitive damages is admitted in the initial stage of the trial. If the jury determines at the conclusion of the initial stage of the trial that Plaintiff is entitled to recover compensatory and punitive damages, then the parties would proceed to a second stage limited to evidence exclusively related to punitive dames

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women. Even if this Court determines that New Jersey law applies to Plaintiff's claim for punitive damages, Plaintiff cannot meet the New Jersey standard for punitive damages, either.

that preferably would be presented without witnesses – i.e., financial information based on the parties' stipulation and evidence admissible through judicial notice.[3]

III. LIST OF PROPOSED WITNESSES

A. Desrene Brown, M.D. (*will call*)

Dr. Desrene Brown is an obstetrician/gynecologist practicing in Ohio. She implanted Ms. Burris's Prolift on August 5, 2008. Dr. Brown will testify that she was aware of the risks associated with Prolift prior to implanting it into Ms. Burris, including the risks of the complications Ms. Burris experienced occurring.

B. Charlotte Owens, M.D. (*will call*)

Dr. Charlotte Owens was a Medical Director at Ethicon from 2003 to 2006. Dr. Owens will testify regarding her knowledge, experience, duties and responsibilities as an OBGYN and Ethicon Medical Director, her clinical experience, and her review of the medical literature. Dr. Owens will testify about her role in launching the Prolift, including the supporting data that Ethicon relied upon prior to the launch of Prolift. Finally, she will testify that Prolift's IFU was adequate and that risks not contained within it were commonly known amongst pelvic floor surgeons.

C. Piet Hinoul, M.D. (*will call*)

Dr. Piet Hinoul joined Ethicon as the Worldwide Medical Director in 2008, and he was responsible for overseeing the safety and effectiveness of Ethicon's pelvic mesh products, including the Prolift, until he left Ethicon in early 2020. Dr. Hinoul will testify regarding his knowledge, experience, duties, and responsibilities as a urogynecologist and Ethicon Medical Director, as well as his clinical experience and review of literature related to the Prolift device.

[3] Defendants request this modified bifurcation pursuant to Fed. R. Civ. P. 42(b) instead of Ohio Revised Code § 2315.21(B) in order to obviate the need for witnesses to testify in both phases.

Finally, he will testify that Prolift's IFU was adequate for its intended audience, pelvic floor surgeons.

D. Salil Khandwala, M.D. (*will call*)

Dr. Salil Khandwala is a urogynecologist who will testify that Plaintiff's pelvic pain was a pre-existing problem not caused by the Prolift. He will testify that it has been commonly known for decades that any surgical intervention done in the vagina, including the surgeries that Ms. Burris had subsequent to her Prolift implant surgery, can cause scar tissue formation, nerve injury, pelvic pain, and pain with intercourse. Dr. Khandwala will also testify that mesh exposure is a well-known complication of mesh surgery that was well known to implanting surgeons at the time of Ms. Burris's implantation and warned about in the Prolift IFU, Surgeon's Resource Monograph, and Ethicon professional education materials. Dr. Khandwala will testify that the Prolift IFU and Ethicon's other professional education materials like the Prolift Surgeon's Resource Monograph adequately describe the risks that are specific and/or unique to Prolift and that the surgical risks and complications Plaintiff's experts say should be included in the Prolift IFU are risks generally known to pelvic floor surgeons. Dr. Khandwala will rely on his education, training, and experience; Ms. Burris's medical records; his review of the literature; his attendance at different medical conferences and professional society meetings; his training of other pelvic floor surgeons in treating pelvic organ prolapse with Prolift; and the materials identified in his expert report and reliance materials.

E. Larry Sirls, M.D. (*may call*)

If called, Dr. Larry Sirls is a urologist who will testify regarding: the mechanism of occurrence of pelvic pain and pain with sex, both with pelvic organ prolapse and with surgical procedures involving and not involving mesh; familiarity to pelvic surgeons and prevalence in the literature of the risks of prolapse surgeries, including mesh exposure, injury to the nerves and

organs, pain with sex, pelvic pain, and urinary dysfunction; and that the contents of the Prolift IFU and the informational and professional materials provided with the Prolift system adequately warned of pertinent potential risks. Dr. Sirls will rely upon his education, training, and experience; his review of the literature; discussions with colleagues; and the materials identified in his expert report and reliance materials.

F. Shelby Thames, Ph.D.[4] (*may call*)

If called, Dr. Shelby Thames is a material science expert who will testify that the Prolene material that comprises the mesh in Prolift does not degrade, "bark," or otherwise disintegrate. He will support this opinion based on the testing and scientific literature contained in his expert report and reliance list.

IV. INDEX OF PROPOSED EXHIBITS

An index of all of Defendants' proposed exhibits containing a brief description of each exhibit, is attached hereto as Appendix A.

V. POTENTIAL EVIDENTIARY ISSUES AT TRIAL

The issues remaining in this case are narrow and focus on the *warnings* made by Defendants about their Prolift product. Yet, Plaintiff has repeatedly attempted to reintroduce issues related to Prolift's *design*—issues which are no longer in this case—back into trial, which will unnecessarily lengthen trial and risk confusing the jury about the proper bases for their deliberations on the remaining failure-to-warn claim.

As this Court knows, Plaintiff initially asserted multiple claims against Defendants, including alleging design-defect and failure-to-warn claims relative to both Prolift and the TVT-

[4] Defendants' Motion to Strike Plaintiff's Supplemental Expert Designations of Jimmy Mays, Ph.D. and Mark Conway, M.D. (Doc. 178) remains pending. It is Defendants' position that testimony from materials experts is not relevant to or admissible in regards to Plaintiff's pending failure-to-warn claim. If, however, the Court disagrees, Defendants reserve their right to call their materials expert, Dr. Thames.

Secur products. TVT-Secur is indicated for the treatment of stress urinary incontinence, an entirely different condition from the pelvic organ prolapse treated by Prolift. Ms. Burris was implanted with TVT-Secur at the same time as the Prolift. This Court granted Defendants summary judgment on Plaintiff's claims related to the TVT-Secur because Plaintiff could not prove an injury from that product (Doc. 105). This Court additionally granted summary judgment as to the Prolift design defect claim because Plaintiff did not have evidence of a practical and technically feasible alternative design. *Id.* As a result, no claims regarding the TVT-Secur and no design-defect claims remain in the case.

Recently, however, Plaintiff has sought to reintroduce design-defect evidence notwithstanding this Court's dismissal of that claim. For example, Plaintiff's deposition designation briefing suggests that Plaintiff intends to revive aspects of her dismissed claims despite the Court's rulings. The Court should not countenance these back-door attempts to inject design claims into this case.

For instance, Plaintiff argues that evidence relating to whether mesh can cause risks by shrinking, contracting, becoming fibrotic, and being too stiff is relevant to her failure-to-warn claim. Doc. # 193 at pp. 3-6, 9, 16, 18. All of these theories, however, relate to the *mechanism* of injury, which is a design-defect question and not part of this case.

Under Ohio law, a failure-to-warn claim tests whether the defendant adequately warned about a known risk of injury associated with the product—here, the Prolift mesh product. Specifically, Ohio law focuses on whether the manufacturer adequately warned about the risk *of an injury*, as opposed to a risk of a theoretical mechanism by which a risk of injury may occur. *See also* Ohio Revised Code § 2307.76(A)(1)(a) (explaining that failure-to-warn liability relates to risks "associated with the product **and that allegedly caused harm for which the claimant**

seeks to recover compensatory damages" (emphasis added). Alleged shrinkage, contraction, fibrosis and stiffness are all contested mechanisms of injury that are irrevocably entwined with Plaintiff's design defect theories. *See* Report of Niall Galloway, attached hereto as Exhibit C, at 9 ("In my opinion, using a material that shrinks and retracts significantly, but in a variable and asymmetric fashion, **is a flaw in design**") (emphasis added).

Arguing that Prolift's warnings are deficient because they do not warn of shrinkage or contraction is synonymous with arguing that Prolift's *design* is defective because it shrinks and contracts. In a failure-to-warn claim, the focus is on whether a manufacturer adequately warned about an alleged injury, not about various hypothetical mechanisms of action that may cause an injury. *See Miller v. Ortho-McNeil Pharmaceutical, Inc.*, No. 3:11 oe 40008, 2013 WL 5939774, at *4 (N.D. Ohio Nov. 5, 2013) (noting that "[a] court . . . may find a warning adequate 'where the adverse effect that was ultimately visited upon the patient was one that the manufacturer specifically warned against.'"). Put another way, the focus is on the alleged risk of *injury*, not the alleged *mechanism* of injury. *See, e.g.*, *Dye v. Covidien LP*, 470 F. Supp.3d 1329, 1340 (S.D. Fla. 2020) ("[T]he inquiry is not whether the manufacturer warned of *defects*, the question is whether the manufacturer warned of *risks*.") (emphasis in original). This makes sense because the focus of an adequate warning is on alerting the user or consumer to the possibility of an injury, not explaining *why* that injury may happen. *Miller*, 2013 WL 5939774 at *4. If Plaintiff is merely able to repackage her design defect theories as warnings, this Court's ruling dismissing the design claim becomes a nullity.

In addition, Plaintiff argues that testimony about Prolift+M should be admitted at trial (Doc. # 193 at 3-6), even though the Court already ruled it should be excluded pursuant to Defendants' Motion *in Limine* No. Plaintiff's rationale for why she should be able to introduce

evidence about Prolift+M is "to establish Defendants' knowledge of the risks of shrinkage prior to the Prolift's market release." *Id.* at p. 6. This explanation strains credulity. Plaintiff is baldly seeking to introduce evidence of a feasible alternative design in the absence of a design defect claim and without expert testimony that Prolift+M was in fact a safer alternative.

There are other potential legal issues that Defendants have addressed in the briefing on deposition designation objections. Additionally, Defendants have filed a briefed-and-pending motion to strike Plaintiff's supplemental expert designations of Jimmy Mays, Ph.D., and Mark Conway, M.D. (Doc. 178). Plaintiff's designation of Dr. Mays—a "materials" expert—is yet another instance of the aforementioned attempts by Plaintiff to revive their design-defect claims under the guise of a failure-to-warn issue. As for Dr. Conway, Plaintiff's late designation of him as a non-retained expert was in violation of the expert disclosure deadline imposed by the MDL Court. Dr. Conway has not been deposed and Defendants should not be prejudiced by having to seek new discovery, including the costs for preparing to take and taking the deposition of an additional expert witness, just because Plaintiff decided to disclose him as holding expert opinions. This Court should therefore limit Dr. Conway to providing testimony as a *fact* witness.

Defendants seek here to highlight for the Court Plaintiff's intention to pursue the case she conceived of upon filing, rather than that prescribed by the evidence and this Court's rulings. Defendants request that the Court limit Plaintiff's presentation of evidence and argument to the product and claim under consideration, Prolift and failure to warn.

VI. RELEVANT MDL *DAUBERT* RULINGS

The Parties have stipulated that this Court may adopt Judge Goodwin's prior *Daubert* rulings on the admissibility of the General Causation experts' opinions and testimony, reserving the parties' rights to 1) appeal those rulings when an appealable judgment is entered in the case, and 2) challenge other evidentiary rulings referred to in those *Daubert* orders, including the admissibility of FDA evidence in this case. Doc. 117. The relevant *Daubert* orders are as follows and attached hereto as Appendix B:

- Order re Jerry Blaivas, M.D. (8/26/16)
- Order re Salil Khandwala, M.D. (9/2/16)
- Order re Dr. Jimmy W. Mays (8/25/16)
- Order re Larry T. Sirls, M.D. (3/29/17)
- Order re Shelby Thames, Ph.D. (9/2/16)

VII. RELEVANT MDL 510(K) RULINGS

The Parties have stipulated that they will be bound by Judge Goodwin's prior rulings in *In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D.W.V.), excluding FDA 510(k) related evidence, subject to preservation of their original objections for purposes of appeal. Doc. 134. Judge Goodwin's Ethicon 510(k) holdings are consistent with his holding in *Cisson v. C.R. Bard, Inc.*, 86 F.Supp.3d 510 (S.D.W.V. 2015).

VIII. PROPOSED VOIR DIRE QUESTIONS

1. Are any of you, or members of your immediate family, related to or acquainted with any of these lawyers?

2. Are any of you acquainted with the Plaintiff?

3. This case involves allegations of personal injury from a pelvic mesh product that was implanted in the Plaintiff, Ms. Burris, to treat pelvic organ prolapse. Please tell me if you have heard or read anything about Ms. Burris' specific case.

4. Prior to today, have you read or heard anything about any lawsuit involving pelvic mesh?

5. Regardless of whether you have heard or read anything about this lawsuit or about any pelvic mesh lawsuit, have you already formed any opinions about Ms. Burris' case?

6. Have you, any member of your family, or a close friend had vaginal surgery or pelvic floor surgery?

7. Have you, any member of your family, or a close friend had a complication in connection with a surgical procedure involving mesh?

8. Have you, any member of your family, or a close friend ever experienced a serious side effect/complication from any medical device or prescription drug?

9. Have you ever decided not to take a medication or use a medical device for yourself or a loved one because you were concerned about safety risks?

10. Have you ever felt that the warnings that come with medical devices or drugs were inadequate or misleading?

11. Do any of you have a negative opinion of pharmaceutical or medical device companies for any reason?

12. Do any of you have a negative opinion of Johnson & Johnson or Ethicon for any reason?

13. Is there anything you think might affect your ability to be fair and impartial to both sides of a personal injury case against a pharmaceutical company?

14. Does anyone believe that if there is potential for a medical device to cause a serious complication in a small number of people, it should not be on the market even if the device is beneficial to many people?

15. Have you ever been seriously injured due to another's negligence and then received only minimal or no compensation?

16. Do any of you feel that even if the plaintiff cannot prove the defendants are responsible for her injuries, you still would be inclined to award her something anyway?

17. The defendants in this case are two corporations - would you have any difficulty treating these corporations the same as you would any individual who is a party to a lawsuit? Would you tend to favor one side over the other?

18. Do you have a family member who has any special training, work experience or education in the following areas: (a) law, law office, or courts; (b) medicine, healthcare, or nursing; (c) pharmaceutical or medical device; (d) government regulation.

Respectfully submitted,

/s/ Erica M. James

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Attorneys for Defendants Ethicon, Inc. and Johnson & Johnson

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2022, a copy of the foregoing *Defendants' Trial Brief* was filed electronically. Service of this filing will be made by operation of the Court's electronic filing system.

/s/ Erica M. James
Erica M. James (0086799)
One of the Attorneys for Defendants
Ethicon, Inc. and Johnson & Johnson